510(k) SUMMARY
Bionime Diabetes Management System

FEB 2 7 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92(C)

The Assigned 510(k) number is: k113007

Date of Summary: October 3rd, 2011

Common Name: Bionime Diabetes Software System; Bionime Diabetes Assistant Software

Regulatory Information:

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the-Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/ Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

Applicant:

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Taichung City, Taiwan 412
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Contact Persons:

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510(k) SUMMARY (Cont.)
Bionime Diabetes Management System

Identification / Product Name:
Bionime Diabetes Management System

Device Description:
The Bionime Diabetes Management System allows the transfer of blood glucose readings from a compatible Bionime Rightest™ Glucose Meter to a PC via USB cable.

The Data analysis features enable the user(s) to view and analyze blood glucose readings from different meal times or time periods up to 90 days. Other features including data tables, trend charts, pie charts, and printed reports are available for viewing and analyzing these readings within the different time slots.

The system includes: 1) Installation CD with setup files for Bionime GP200 Diabetes Assistant Software and Rightest™ PC Link Adapter Driver, 2) GP550 PC Link Adapter.

Intended Use:
The Bionime Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from Rightest® Glucose meter(s) to a personal computer for the purpose of viewing, analyzing and printing the blood glucose readings, as well as to backup and to recover users' profile and data. Bionime Rightest™ GM550 and GM250 meters are compatible with Bionime Diabetes Management System.

The Bionime Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed healthcare professional.

Predicate Kit:
The Bionime Diabetes Management System is substantially equivalent to the predicate device noted below:

Device Name: Glucofacts® Deluxe Diabetes Management Software
510k No.: k091820
Device Company: Bayer Healthcare, LLC

Technology Characteristics:
The Bionime Diabetes Management System (GP200 Diabetes Assistant Software) is used to capture Rightest™ blood glucose meter readings and graphically display the information. It utilizes the standard statistical and graphical techniques to facilitate the review of glucose readings by individual user or health care professionals.

Performance:
The product performance characteristics of Bionime Diabetes Management System were assessed through internal and external performance and validation studies, include a consumer study with 29 lay users.

The results of these studies demonstrate satisfactory performance of Bionime Diabetes Management System (GP 200 Diabetes Assistant Software and GP550 PC Link Adaptor), and it is easy to use and the results are understandable by the users.

Conclusion:

The results of the verification and validation studies of the Bionime Diabetes Management System demonstrated that the product is safe and effectiveness in the hands of lay users and health care professionals. The product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bionime Corporation
c/o Feng-Yu Lee
IVDD Regulatory Consultant
27001 La Paz Road, Suite 266B
Mission Viejo, CA 92691

FEB 27 2012

Re: k113007
Trade Name: Bionime Diabetes Management System Software
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: February 13, 2012
Received: February 16, 2012

Dear Mrs. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k

Device Name: **Bionime Diabetes Management System (BDMS)**

Indication For Use:

The Bionime Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from Rightest® Glucose meter(s) to a personal computer for the purpose of viewing, analyzing and printing the glucose readings, as well as to backup and to recover users' profile and data.

The Bionime Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed healthcare professional.

Prescription Use __X__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k113007